Washington State Health Care Authority

Health Technology Clinical Committee

Date: June 14, 2024
Time: 8:00 a.m. – 12:30 p.m.
Location: Webinar
Adopted: July 26, 2024

Meeting materials and transcript are available on the **HTA website.**

HTCC Minutes

Members present: John Bramhall, MD, PhD; Clinton Daniels, DC, MS; Janna Friedly, MD, MPH; Chris Hearne, DNP, MPH; Conor Kleweno, MD; Christoph Lee, MD, MS; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD; Jonathan Sham, MD; Tony Yen, MD
Clinical experts: Amy Yuen, MD

HTCC Formal Action

1. **Welcome and Chair remarks:** Dr. Rege, chair, called the meeting to order; members present constituted a quorum.
2. **HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines, and an overview of the HTA program.
3. **Previous meeting business:**

   May 17, 2024 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

   Action: 10 committee members approved the May 17, 2024 meeting minutes.

   Vote on spinal cord stimulation draft findings and decision: Public comments and draft findings reviewed.

   Action: Ten committee members voted to finalize spinal cord stimulation draft findings and decision.

   Vote on bariatric surgery draft findings and decision: Public comments and draft findings reviewed.

   Action: Ten committee members voted to finalize bariatric surgery draft findings and decision.
4. **Tumor treating fields**

   HTCC reviewed petition and supplemental materials.

   Action: Ten committee members voted that the evidence presented would not change the previous determination
5. **Whole genome sequencing (WGS)**

   HTCC discussion and action:

   Discussion

The committee drafted coverage criteria for use of WGS. Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee discussed and voted separately on the evidence for the use of WGS. The committee decided that the current evidence on WGS is sufficient to determine coverage with conditions. The committee considered the evidence, public comment and expert input, and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover WGS with conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Whole genome sequencing	0	9	0

Discussion

The committee reviewed and discussed the available studies for use of WGS. Members drafted coverage criteria for the use of WGS and voted on a draft findings and decision. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed as well as clinical application.

Decision

Limitations of coverage:

Whole genome sequencing (WGS) is a covered benefit with conditions for the evaluation of unexplained congenital or neurodevelopmental or neurodegenerative disorders in a phenotypically affected individual when **ALL of the following** criteria are met:

1. A board-certified or board-eligible Medical Geneticist, or an Advanced Practice Nurse in Genetics (APGN) credentialed by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC), who is not employed by a commercial genetic testing laboratory, has evaluated the patient and family history, and recommends and/or orders the test; and

2. A genetic etiology is considered the most likely explanation for the phenotype, based on **EITHER of the following**;

   - Multiple abnormalities affecting unrelated organ systems, (e.g. multiple congenital anomalies); or
   - **TWO of the following criteria are met:**
     - Significant abnormality affecting at minimum, a single organ system,
     - Unexplained cognitive changes in adulthood,
     - Profound global developmental delay[1], or intellectual disability[2] as defined below,
     - Family history strongly suggestive of a genetic etiology, including consanguinity,
     - Period of unexplained developmental regression (unrelated to autism or epilepsy),
     - Biochemical findings suggestive of an inborn error of metabolism where targeted testing is not available; and

3. Other circumstances (e.g. environmental exposures, injury, infection) do not reasonably explain the constellation of symptoms; and
4. Clinical presentation does not fit a well-described syndrome for which single-gene or targeted panel testing (e.g., comparative genomic hybridization [CGH]/chromosomal microarray analysis [CMA]) is available; and
5. The differential diagnosis list and/or phenotype warrant testing of multiple genes and **ONE of the following**:
    - WGS is more efficient and economical than the separate single-gene tests or panels that would be recommended based on the differential diagnosis (e.g., genetic conditions that demonstrate a high degree of genetic heterogeneity); or
    - WGS results may preclude the need for invasive procedures or screening that would be recommended in the absence of testing (e.g. muscle biopsy); and
6. A standard clinical work-up has been conducted and did not lead to a diagnosis; and
7. Results will impact clinical decision-making for the individual being tested; and
8. Pre- and post-test counseling is performed by an American Board of Medical Genetics or American Board of Genetic Counseling certified genetic counselor.

Non-covered indicators:

WGS is not covered for:

- Carrier testing for "at risk" relatives.
- Prenatal or pre-implantation testing.

Definitions:

[1] **Global developmental delay (GDD)** is used to categorize children who are younger than five years of age.

GDD is defined as a significant delay[2] in two or more developmental domains, including gross or fine motor, speech/language, cognitive, social/personal, and activities of daily living and is thought to predict a future diagnosis of ID. Such delays require accurate documentation by using norm-referenced and age appropriate standardized measures of development administered by experienced developmental specialists, or documentation of profound delays based on age appropriate developmental milestones are present.

Reference: *Comprehensive Evaluation of the Child With Intellectual Disability or Global Developmental Delays Pediatrics 2014;134:e903–e918. Page e905*

Significant delay is typically defined as performance two standard deviations or more below the mean on age-appropriate, standardized, normal-referenced testing.

[2] **Intellectual disability (ID)** is a life-long disability diagnosed at or after age five when intelligence quotient (IQ) testing is considered valid and reliable. The Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association (DSM-V), defines patients with ID as having an IQ less than 70, onset during childhood, and dysfunction or impairment in more than two areas of adaptive behavior or systems of support.

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Based on the information provided in the systematic review, there is no NCD for whole genome sequencing.

The committee discussed clinical guidelines identified from the following organizations:

- Medical Genome Initiative (MGI), 2024, Evidence review and consideration for use of first-line genome sequencing to diagnose rare genetic disorders
- National Society of Genetic Counselors (NSGC), 2023, Genetic testing and counseling for the unexplained epilepsies: an evidence-based practice guideline
- National Institute of Health and Care Excellence (NICE), 2022, Epilepsies in children, young people, and adults
- EuroGentest, 2022, Recommendations for WGS in diagnostics for rare diseases
- American College of Medical Genetics and Genomics (ACMG), 2021, Exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability evidence-based guideline
- Canadian College of Medical Geneticists, 2015, The clinical application of genome-wide sequencing for monogenic diseases in Canada

The recommendations of the guidelines vary. The committee's determination is consistent with the noted guidelines.

HTA staff will prepare a findings and decision document on use of spinal cord stimulation for the treatment of selected conditions for public comment to be followed by consideration for final approval at the next committee meeting.

6. Meeting adjourned